No. 23-2017

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

DNA GENOTEK INC.,

Plaintiff-Appellant,

v.

SPECTRUM SOLUTIONS LLC,

Defendant-Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA IN CASE NO. 3:21-cv-00516-RSH-DDL, JUDGE ROBERT S. HUIE

BRIEF OF SPECTRUM SOLUTIONS L.L.C.

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December 22, 2023

Claim 1, U.S. Patent No. 10,619,187

1. A device for receiving and preserving nucleic acid in a biological sample, said device comprising:

a. one or more walls defining a containment vessel having a top having an opening, and a closed bottom having a sample receiving area for holding said biological sample, said opening for receiving a liquid sample and for sealably receiving a sealing cap, said top having an opening for receiving a biological sample from the mouth of a user and further comprising at least one marking on said one or more walls which corresponds to a fluid volume in the sample receiving area;

b. a reagent compartment having a barrier, said barrier sealing and containing reagents in said reagent compartment and capable of disestablishment to release said reagents into the sample receiving area;

c. reagents in the reagent compartment for preserving nucleic acids potentially present in the sample wherein said reagents comprise a denaturing agent, a chelator and a buffer agent; and,

d. the sealing cap, whereby the device is configured such that, when sealably closing said opening with said sealing cap, the barrier mechanically disestablishes to release said reagents to form a mixture of reagents and said biological sample wherein said buffering agent maintains a pH of said mixture equal to or above 5.0 to preserve nucleic acids potentially present in the sample.

Claim 1, U.S. Patent No. 11,002,646

1. A kit for collecting and preserving a biological sample, the kit comprising:

a sample collection vessel, the sample collection vessel comprising: a sample collection reservoir having an opening configured to receive the biological sample from a user into the sample collection reservoir; a connection member disposed on an exterior portion of the sample collection vessel and adjacent to the opening;

a cap, the cap comprising: a reagent chamber configured to store a reagent; and a complementary connection member configured to engage the connection member of the sample collection vessel; and

a movable annular valve configured to associate with the cap and with the opening of the sample collection reservoir, the movable armular valve comprising: an inner cylinder in fluid-tight association with the cap and comprising a sidewall, the sidewall comprising a fluid vent; and

an outer cylinder in fluid-tight association with the inner cylinder and associated with the opening of the sample collection reservoir, the outer cylinder comprising an aperture defined by an interior sidewall of the outer cylinder,

wherein the aperture accommodates at least a portion of the inner cylinder,

wherein the interior sidewall obstructs the fluid vent when the movable annular valve is closed, and

wherein the interior sidewall does not obstruct the fluid vent when the movable annular valve is open.

CERTIFICATE OF INTEREST

Counsel for Appellant Spectrum Solutions L.L.C., certifies the following:

1. The full name of every party or amicus represented by me is:

Spectrum Solutions L.L.C.

2. The name of the real party in interest represented by me is:

N/A.

3. All parent corporation and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Spectrum Buyer, LLC; Spectrum Intermediate, LLC

4. Other than those who have already made an appearance in this Appeal, the name of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this Court are: Nicholas M. Zovko, Stephen W. Larson, Paul Conover and Yanna S. Bouris, of Knobbe, Martens, Olson & Bear, LLP.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by the Court's decision in the pending appeal are as follows:

Spectrum Solutions LLC v. DNA Genotek Inc., IPR No. 2022-01347 (PTAB).

6. Information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):

None.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 22, 2023 By: /s/ *Ali S. Razai*
Ali S. Razai, *Principal Counsel*

Attorneys for Defendant-Appellee
Spectrum Solutions L.L.C.

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OTHER AUTHORITIES

STATEMENT OF RELATED CASES

There have been no previous appeals of this civil action. U.S. Patent No. 11,002,646 at issue on this appeal is the subject of IPR2022-01347 currently pending before the U.S. Patent Trial and Appeal Board. The Board's final decision in the IPR is due by February 12, 2024. The IPR involves an identical issue presented on this appeal, namely the construction of "preserving a biological sample," albeit in the context of whether the claims of the patent are valid. Thus, the IPR may ultimately be affected by the decision in this appeal.

STATEMENT OF THE ISSUES

1. Where the district court granted summary judgment of non-infringement of the '187 patent based on a finding that "no reasonable jury could conclude that the accused products literally satisfy the 'containment vessel having a top having an opening…said opening for receiving a liquid sample and for sealably receiving a cap' claim limitation based on the structure identified by Genotek," whether Genotek's challenge to the district court's construction of "reagent compartment" is moot because the district court's summary judgment of non-infringement did not rely on that claim limitation.

2. If Genotek's claim construction challenge of "reagent compartment" is not moot, whether the district court correctly construed "reagent compartment" to be a "region or section of the containment vessel."

3. Whether the district court correctly construed "preserving a biological sample" in the preamble of the '646 patent (a) as limiting and (b) to mean "preventing the cells in the biological sample from having their antigens degraded such that they can be purified or enriched based on their antigens, and preventing alterations in the cellular epigenome" in accord with an explicit definition in the specification.

INTRODUCTION

Genotek's appeal of the district court's summary judgment of non-infringement of the '187 patent is moot. That judgment was not based on the "reagent compartment" limitation addressed in Genotek's appeal. Rather, it was based on the container/containment vessel limitation, which requires the "containment vessel" to have "a top having an opening … said opening for receiving a liquid sample and for sealably receiving a cap." Genotek presented an infringement case, supported by expert testimony, that the accused device has a tube and cap that together satisfy this limitation. The district court accepted Genotek's evidence and granted summary judgment of non-infringement because no reasonable jury could "conclude that the top of the structure identified by Genotek has an opening for receiving a cap." Appx91. Because Genotek does not challenge the district court's bases for summary judgment of non-infringement of the '187 patent, the appeal is moot as to that patent.

Even if Genotek's challenge to the construction of "reagent compartment" were not moot, the appeal on the '187 patent nonetheless fails because the district court's construction was correct. The district court correctly construed the "reagent compartment" of the claimed device as a "region or section of the containment vessel." The specification clearly states that the region containing the composition

for preserving the nucleic acids (i.e., the reagent compartment) of the invention is located within the container. The district court correctly rejected that these clear statements were merely describing a preferred embodiment and instead found that they describe the invention as a whole. Appx33.

The district court's construction was further supported by what Genotek omitted from its patent application that issued as the '187 patent. Genotek's provisional application disclosed a sample collection device with a reagent compartment in the cap of the device. When Genotek filed its non-provisional application it deleted that embodiment and described the invention as limited to a device with a reagent compartment in the container. The construction was also supported by Genotek's later explicit characterization of the '187 patent as limited to a device with a reagent compartment in the container.

As to the '646 patent, Genotek only challenges the construction of the term "preserving a biological sample" in the claim preamble. Because the district court correctly construed that term as a limitation of the invention, the district court's grant of summary judgment of non-infringement should be affirmed. First, the claim preamble provides antecedent basis for "the biological sample" recited in the body of the claim. Although the full preamble is not recited in the claim body, the preamble was correctly treated as a limitation because "biological sample" is

intertwined with the broader preamble phrase "collecting and preserving a biological sample." Second, the preamble is limiting (and requires preservation of cells) because the specification underscores that preserving cells of a biological sample is an important feature of the invention and also provides an explicit definition for preserving cells of a sample.

STATEMENT OF THE CASE AND THE FACTS

In 2019, Spectrum developed and began commercializing a novel device for collecting saliva samples for molecular diagnostic testing: the SDNA saliva collection device.[1] Spectrum's SDNA device was the nation's first home saliva-collection kit for COVID-19 PCR testing. Appx956-957. In March 2021, after Spectrum's SDNA device had become the gold standard for this use, Genotek sued Spectrum, alleging that the SDNA device infringed its '187 patent. Appx223. Genotek later filed an amended complaint alleging that the SDNA device also infringed the '646 patent. Appx294.

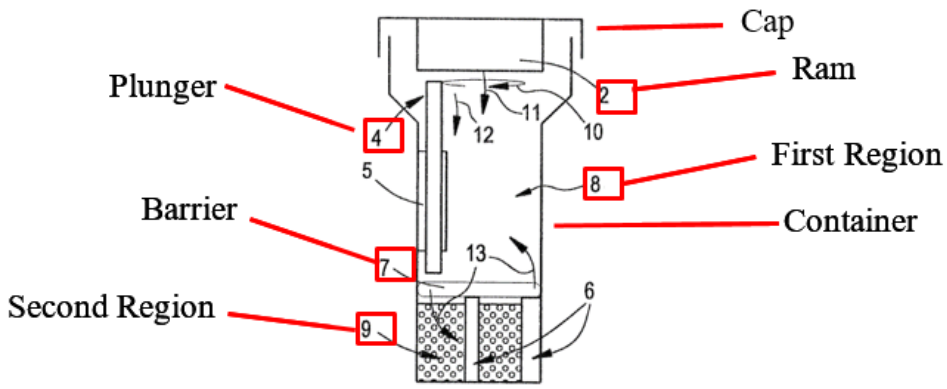
A. The Asserted '187 Patent

Per the '187 patent specification, "[t]he present invention relates to compositions and methods for preserving nucleic acids at room temperature for extended periods of time …." Appx131 (1:23-25). The patent includes substantial detail about the reagents that make up the composition of the invention. Appx135-136 (9:1-11:67). The invention features a composition that includes a denaturing agent, a chelator, and a buffer. Appx135 (9:22-28). The composition destroys or

[1] Though the SDNA device had three numerical designations, SDNA-1000, SDNA-2000 and SDNA-3000, the products are identical. Appx3806-07 (110:15-111:25).

lyses the cells contained within a biological sample. The patent explains how the composition works: "When sputum is mixed with a composition of the present invention, cells are disrupted, nucleic acids are liberated from the cells, membranous material [i.e., the cell membrane] is solubilized, proteins are stripped from the nucleic acids, and protein digestion begins." Appx137 (13:38-42).

The '187 patent also describes a device that contains the reagent composition and permits collection of the biological sample and mixing the sample with the reagent composition. As depicted below, the device includes a container with a cap.



Appx130 (Fig. 11 (annotations added)).

The specification describes the device as follows:

> The device includes: a container that has a first region for collecting a biological sample and a second region containing a composition for preserving a nucleic acid, a barrier between a first region and a second region that keeps the sample and composition separate, a means for closing the container, and a means for disturbing the integrity of the barrier, such that the composition is capable of contacting the bodily sample.

Appx137 (14:51-58). The barrier that separates the two compartments (regions) of the container can be a pierceable membrane or pivoting sealing disc. Appx130 (Fig. 11) (annotated above); Appx138 (15:17-20, 15:33-36). The device also includes structures that displace the barrier to allow the reagents and the sample to mix in the container. Appx138 (15:37-49).

The specification includes a Summary of the Invention that lists seven aspects of the invention, one of which is the device of the invention. Appx132-133 (3:46-6:65). The other aspects in the Summary of the Invention relate to a composition for preserving nucleic acids and various methods. *See* Appx132 (3:61-64 (first aspect)); Appx133 (5:35-39 (second aspect); 5:46-50 (third aspect); 5:57-62 (fourth aspect); 6:6-13 (fifth aspect); 6:46-56 (seventh aspect)). The sixth aspect, which relates to the device of the invention, provides:

> In a sixth aspect, ***the invention features a device*** for preserving and/or isolating a nucleic acid obtained from a biological sample. ***The device includes***: a container that has a first region for collecting a biological sample and ***a second region containing a composition for preserving a nucleic acid***, a barrier between the first region the second region that keeps the biological sample and the composition separate, a means for closing the container, and a means for disturbing the integrity of the barrier such that the composition is capable of contacting the biological sample.

Appx133 (6:26-36) (emphasis added). The seventh aspect features a "method of manufacturing a device for preserving a nucleic acid in a biological sample," which

includes providing a container having a region for containing the reagent composition. *Id.* (6:46-50).

The remainder of the specification is in accord with the Summary of Invention, namely describing the device of the invention as providing a reagent in a region of the container, and a separate lid that closes the container. Appx137-138 (14:49-60, 15:1-13, 15:33-49).

B. Genotek's Provisional Application

The '187 patent claims priority to three provisional applications, including provisional application no. 60/386,398 ("'398 provisional"). Appx118. The '398 provisional describes a sample collection device or tube having a reagent compartment. Appx3182. The '398 provisional describes one embodiment where the reagent compartment is in the cap of the device and another embodiment where the reagent compartment is in the container. Although the '187 patent bodily incorporates the embodiment with a reagent compartment in the container, it omits any reference to a device with the reagent compartment in the cap.

In the first embodiment of the provisional the "compartment is the underside of the cap of the container." Appx3185. The provisional describes this embodiment as follows:

Figure 2. Tube design 'B'. In this embodiment, the tube is of design A in which the lid has been modified: It contains a small bag (3) containing about 2 milliliters of DNA preserving composition described above or other desired agent. The cap and bag are designed such that the action of tightening the cap both locks the cap and releases the contents of the bag, allowing the DNA preserving solution to mix with the saliva.

FIGURE 2

Appx3186 (emphasis original); Appx3190.

The second embodiment described in the provisional is depicted in Figures 3-5, which have the reagent compartment at the bottom of the container. In one version of this embodiment (Figure 3), a septum is used to seal the reagent composition in the bottom of tube. The "septum is made of polyethylene or similar material that can be easily pierced," thereby releasing the composition to mix with the sample. Appx3186.

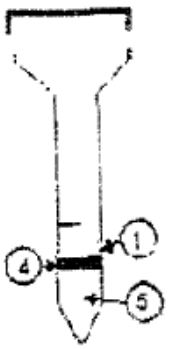


FIGURE 3

Appx3190.

In the second version of this embodiment (Figures 4 and 5), a sealing disk is used in place of the pierceable septum. The sealing disk is displaced by a plunger that is contacted by a ram when the cap is applied (Figure 5), thereby releasing the composition to mix with the sample. Appx3186.

FIGURE 4

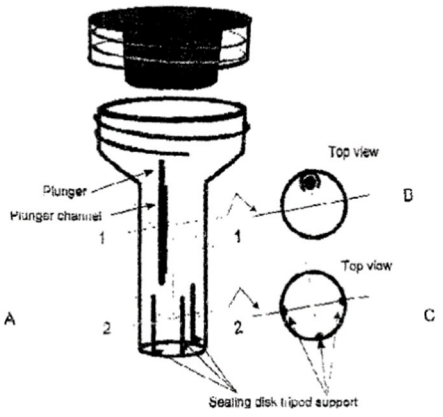
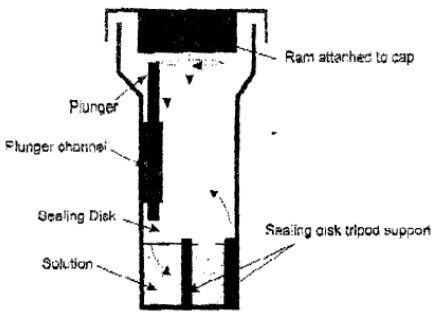


FIGURE 5



As cap is tightened on thread, ram descends and pushes on plunger, which pushes on sealing disk, which is tipped and releases the solution

Appx3191.

When Genotek filed its non-provisional application that resulted in the ’187 patent, it deleted all references to the embodiment with a reagent compartment in the

cap, including Figure 2 and the associated text describing it. Genotek included only the embodiments with the reagent compartment in the container. *Compare* Appx129-130 (Figs. 10-11) *with* Appx3191 (Figs. 4-5).

The '187 patent specification includes a statement incorporating by reference the disclosure of the '398 provisional. Appx131 (1:18-19). Genotek, however, never bodily incorporated into the '187 patent the '398 provisional's description of a device having the reagent compartment in the cap.

C. Genotek's Later Characterizations of the '187 Patent

Genotek later filed an application describing and claiming a sample collection device with a reagent compartment in the cap of the device. Specifically, in 2006 (four years after the earliest priority date of the '187 patent), Genotek filed an application leading to U.S. Patent No. 8,221,381 ("the '381 patent"). Appx1569. The '381 patent, like the '187 patent, discloses a sample collection device with a reagent chamber for releasably storing a reagent composition. However, in the '381 patent the reagent compartment is in the cap of the device as depicted in Figure 24 below.

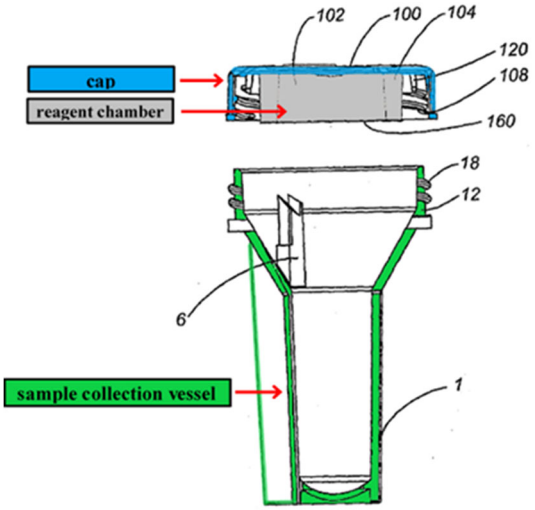


FIG. 24

Appx1585 (annotations added); Appx1587 (4:24-33).

The ’381 patent specifically claims the reagent compartment in the lid of the device: “1. A container system for releasably storing a substance [e.g., the reagent composition], comprising… b) a lid… comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within the reservoir….” Appx1591-92 (12:59–13:4).

In the background of the ’381 patent, Genotek cited and distinguished a publication of the ’187 patent at issue here. Specifically, Genotek described the ’187 patent (referenced as its PCT publication) as follows:

> International PCT application WO 2003/104251 describes a container for collecting a biological sample…. This container has a first region for collecting a biological sample, a second region containing a composition for preserving nucleic acid, and a barrier between the first region and a second region.

Appx1686 (1:50-59).

The ’381 patent was later challenged in an IPR. The ’187 patent was asserted as prior art to that patent (the ’187 patent was referred to as “Birnboim” in the IPR proceedings). Appx1524. The petitioner argued, *inter alia*, that it would have been obvious to modify Birnboim to put the reagent compartment in the lid as was claimed in the ’381 patent. In opposing the IPR, Genotek represented that Birnboim describes a “very different device[]” than those with a reagent compartment in the lid because Birnboim has “a reagent below a plastic cover in a container.” Appx1562-63. The PTAB denied institution of the petition. Appx1511-14. The PTAB explained: “As Patent Owner [Genotek] points out, Petitioner does not explain sufficiently why one of ordinary skill in the art would have considered combining the container of Birnboim with certain features of the container of O’Donovan [a device with a reagent compartment in a lid] to arrive at the claimed invention.” Appx1512.

D. The Asserted ’646 Patent

The ’646 patent also relates to compositions and a device for preserving a biological sample, but in a quite different manner than the ’187 patent. Rather than *destroying* cells to release the nucleic acids like the ’187 patent, the ’646 patent invention is directed to *preserving* the cells in the biological sample. The ’646 patent addressed the need for a device that enabled a biological sample to be collected and

its cells preserved so that particular cells could be isolated and their genetic makeup (epigenome) could be profiled. Appx174 (4:47-49). Consistent with addressing this need, the patent specification repeatedly discusses preserving the cells in the collected sample.

For example, the Abstract states that the "disclosure relates to devices, solutions and methods for collecting and processing samples of bodily fluids containing ***cells***;" "the disclosure generally relates to…the isolation and ***preservation of cells*** from saliva and other bodily fluids." Appx142 (emphasis added).

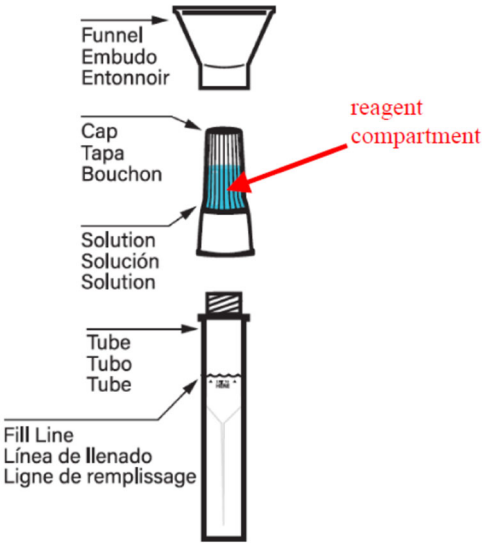
The patent's Field of the Disclosure explains that the patent relates to the "isolation and preservation of cells" from bodily fluids. Appx173 (1:25-27). The patent's Background of the Invention describes the need the invention addressed—a device that enables collecting and preserving cells so they can be isolated for epigenetic studies. Appx173-174 (2:63-67, 3:57-59, 4:37-49). The patent's Summary of the Disclosure also repeatedly discusses preserving and isolating cells. Appx174-176 (4:56-61, 6:5, 6:31, 6:38, 6:50-51, 6:61-62, 7:7-11, 7:54-55, 8:11-14). Nowhere does the Summary of Disclosure mention preserving anything other than the cells of a bodily fluid. The patent's Detailed Description of the Embodiments also repeatedly describes the preservation and isolation of cells. Appx177-182

(9:44-47, 9:63-65, 16:9-10, 16:11-12, 16:23-24, 16:38-40, 16:44, 16:50, 16:62, 17:15-16, 17:20, 17:30-31, 19:14-15). And finally, the sole example of the patent describes "Isolating T-Cells from a Bodily Fluid (e.g., Saliva)." Appx181-182 (18:61-19:40); *see also* Appx171-172 (Figs. 8-10 (demonstrating yield of isolated T-cells after storage in preservation solution)).

Claim 1 of the '646 patent is directed to "a kit for collecting and preserving a biological sample." Appx183. Neither "preserving a biological sample" nor even "biological sample" appears anywhere in the specification of the '646 patent. The specification does, however, provide an explicit definition for "preserving cells, stating, "[f]or purposes of the disclosure, 'preserving cells' means preventing the cells from having their antigens degraded, such that they can be purified or enriched based on their antigens, and preventing alterations in the cellular epigenome." Appx180 (16:23-27).

E. Spectrum's Accused SDNA Device

Genotek alleged that Spectrum's SDNA device infringed both the '187 patent and the '646 patent. The SDNA device, shown below, includes: a funnel, a cap, and a container or tube. The cap includes a compartment containing reagents.



Appx3635-37; Appx3810-11.

The SDNA device is supplied with the funnel attached to the container. A user deposits a saliva sample into the funnel. The funnel is removed and discarded. The cap is then attached to the container. Screwing the cap onto the container causes the reagent solution stored in the cap to be released into the container. Appx3811. The use of the SDNA device is visually depicted below.

Appx3810.

The reagents in the SDNA device include denaturing agents (guanidine thiocyanate and alcohol), a buffer (Tris), and a chelator (EDTA). Appx3649; Appx3791; Appx3793; Appx3796-97. The reagents do not preserve cells in the saliva sample. Rather, the reagents lyse cells, liberate nucleic acids from the cells, and preserve the nucleic acids. Appx3786 (32:13-17); Appx3788 (34:9-12).

F. The District Court's Claim Constructions

1. The '187 Patent

The parties disputed the meaning of several terms in the '187 patent, including: (1) "containment vessel"; (2) "said opening for receiving a biological sample from the mouth of a user"; and (3) "reagent compartment." The district court issued a 72-page claim construction order, which included the following constructions:

1. "containment vessel" construed as "container," Appx21-23;
2. "said opening for receiving a biological sample from the mouth of a user" construed as "the opening is able to receive a liquid biological sample directly from the mouth of the user," Appx24-31; and
3. "reagent compartment" construed as a "region or section of the containment vessel," Appx31-44.

Genotek here challenges only the construction of "reagent compartment." In construing that term, the district court noted Spectrum's argument that "Genotek []

expressly disavowed any claim scope that would cover devices with a reagent compartment located in the cap." Appx31-32. The district court agreed, finding: "the specification of the '187 Patent contains several clear disclaimers explaining that the invention claimed in the '187 Patent features a device with the reagent compartment in the container (*i.e.*, the containment vessel)." Appx44. The district court found the disclaimer in the specification was supported by Genotek's "deletion of any explicit disclosure of the reagent compartment being in the cap/lid from the '398 Provisional and by DNA Genotek's statements during IPR proceedings describing the scope of the claimed invention." *Id.*

2. The '646 Patent

The parties disputed the meaning of several terms for the '646 patent, including the preamble phrase "preserving a biological sample" and whether the preamble served as a limitation of the claimed invention. The district court held that the preamble phrase "preserving a biological sample" was limiting and construed the term to mean "preventing cells in the biological sample from having their antigens degraded such that they can be purified or enriched based on their antigens, and preventing alterations in the cellular epigenome." Appx59-65. The construction followed an explicit definition in the specification for "preserving cells." Appx180 (16:23-27).

G. The Summary Judgment of Non-Infringement

Following claim construction, Spectrum moved for summary judgment of non-infringement of both asserted patents. Genotek opposed.

Despite the district court's holding that the claimed reagent compartment of the '187 patent was in the container and not the cap, Genotek maintained its claim for infringement by contending that the cap of the SDNA device was part of the container. Appx3640. Genotek argued:

> The Accused Product has a "reagent compartment." It is located in the cap before its device is used, but once the cap is placed on the collection tube as intended, the cap and the collection tube form the required "container." Without a cap, the preserved sample is not "contained."

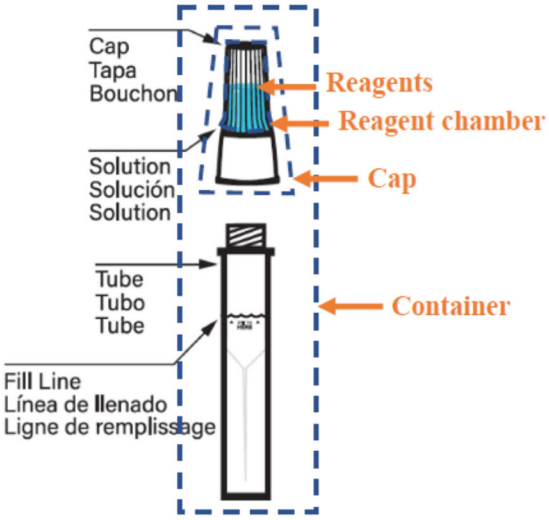
Appx3835 (citing Appx4037-38).

In opposing summary judgment, Genotek largely relied on an expert declaration of Dr. Steven Wereley who opined that the container of the SDNA device includes *both* the cap and the tube. Genotek argued against summary judgment:

> The jurors will also have the testimony of Dr. Steven Wereley…. He explained that the Accused Product's "cap" and "tube" (Spectrum's words) combine to make a single "container." [Appx4037-41] The cap houses what Spectrum calls a "reagent chamber." Because the "cap" is part of the overall "container," the Accused Product's "reagent chamber" is the required "reagent compartment," which is a "region or section of the containment vessel." [Appx4054-56].

Appx3835-36 (joint appendix citations to Wereley Report added via brackets). Genotek illustrated its argument using an annotated depiction of the SDNA device

showing that the cap and the tube together make up the claimed container/reagent compartment:



Appx3836; Appx4049.

According to Genotek, "Dr. Wereley explained the problems solved by the '187 patent, namely being able to collect, mix, preserve, and ship biological samples. ([Appx4034-35].)" Appx3836. Genotek further quoted Dr. Wereley's testimony that "[t]o meet the 'contain' function of a container, the container must include the cap—if the container did not include the cap, then the preservative sample mixture could not be shipped; the tube alone would be insufficient to contain the mixture during shipment." Appx3836 (quoting Appx4037-38). And further, Genotek argued that "[a] juror accepting this testimony would conclude that the Spectrum device

satisfied both the 'containment vessel' (container) and 'reagent compartment' limitations." Appx3836.

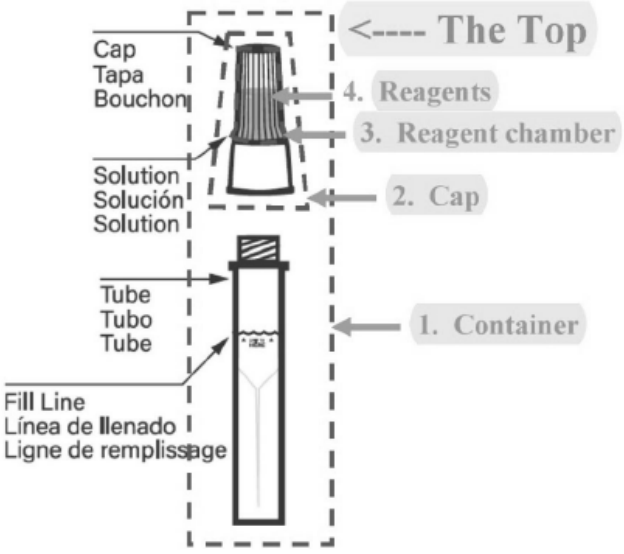
In opposing summary judgment of the '187 patent, Genotek also submitted an expert declaration of Dr. Michael Metzker. Dr. Metzker opined that the SDNA device met the chemical limitations of the '187 patent, namely that it had "reagents in the reagent compartment for preserving nucleic acids potentially present in the sample wherein said reagents comprise a denaturing agent, a chelator and a buffer." Appx3931-32.

Genotek also relied on Dr. Metzker's declaration in opposing summary judgment on '646 patent. For the '646 patent, Metzker opined that the SDNA device, despite having the reagent composition of the '187 patent invention that lyses cells, nevertheless preserves cells in a biological sample as the '646 patent required. Appx3950-51. Consistent with the cell lytic properties of the solution in the SDNA device, Dr. Metzker's testing proved that samples contacted with the solution of the SDNA device showed "lower cell percentages" compared with those that were not contacted with the solution. Appx3958.

The district court rejected Genotek's arguments and granted summary judgment of non-infringement on both patents. As to the '187 patent, the district court found Genotek's infringement theory presented in opposition to summary

judgment was "based on an untimely and flawed claim construction," namely the "contention that the claimed 'sealing cap' is part of the claimed 'containment vessel.'" Appx85. The district court also held that if the construction had not been waived, it was erroneous. Appx87.

The district court held that even if the waived and incorrect construction were adopted, it could not result in infringement because the '187 patent claims also require a "containment vessel" having "a top having an opening…said opening for receiving a liquid sample and for sealably receiving a cap." Appx88-89. At the summary judgment hearing, Genotek's counsel conceded that the plain meaning of the word top is "uppermost part." Appx88, n.4; Appx5783-84. In the summary judgment order, the district court noted this concession aligns with the plain meaning of top, and provided additional annotation to Genotek's own diagram of the accused device point to "The Top":



Appx88-89. The district court concluded, "no reasonable jury could conclude that the accused products literally satisfy the 'containment vessel having a top having an opening . . .' claim limitation based on the structure identified by Genotek." Appx92. The district court also held Genotek waived any theory of infringement under the doctrine of equivalents. Appx97.

As to the '646 patent, the district court noted that Genotek's expert (Dr. Metzker) opined that the accused product satisfied the reagent limitations of the '187 patent. The district court also noted that '187 patent explains that the reagent composition has the following effect on a sample: "When sputum is mixed with a composition of the present invention, cells are disrupted, nucleic acids are liberated from the cells, membranous material is solubilized, proteins are stripped from the nucleic acids, and protein digestion begins." Appx106. The district court recognized this was an undisputed fact: "And Spectrum also concedes that the accused solution performs in this manner, see ECF No. 231-1 at 1-2, 14-17 [Appx3507-08, Appx3520-23], meaning that it is not only Dr. Metzker's opinion, but it is an undisputed fact in this case that the accused solution performs in that manner." Appx107. The district court then went on to address how Dr. Metzker's testing could not change the undisputed fact that the SDNA device did not preserve cells of a biological sample as defined in the '646 patent. Appx107-111.

SUMMARY OF THE ARGUMENT

The district court's summary judgment of non-infringement should be affirmed for three reasons.

1. ***Genotek's appeal as to the '187 patent is moot***. The '187 patent claims require "a containment vessel having a top having an opening…said opening for receiving a liquid sample and for sealably receiving a sealing cap." Genotek opposed summary judgment of non-infringement by asserting the tube and the cap of the accused SDNA device constituted the claimed "containment vessel," which the district court had construed as "container." Genotek supported its opposition with expert testimony applying the claim language to the accused SDNA device in the same manner. The district court granted summary judgment because "no reasonable jury could conclude that the accused products literally satisfy the 'containment vessel having a top having an opening . . .' claim limitation based on the structure identified by Genotek." Appx92. Genotek's appeal does not challenge that ruling. Genotek only challenges the district court's construction of a separate limitation, "reagent compartment," which was not the basis of the summary judgment. The appeal is therefore moot.

2. ***Even if Genotek's appeal were not moot, the district court correctly construed "reagent compartment" as a "region or section of the containment vessel."*** The district court correctly determined the specification disclaimed a device having a reagent compartment anywhere other than in the container. The specification repeatedly characterized the device of the invention as having a container with a region for containing a reagent composition. The construction was supported by Genotek's omission of any embodiment having a reagent compartment anywhere other than in the container when Genotek filed the application leading to the '187 patent despite disclosing such embodiment in a provisional application. The construction was also supported by Genotek's later explicit characterization of the '187 patent as limited to a device with a reagent compartment in the container.

3. ***The district court correctly construed "preserving a biological sample" in the preamble of the '646 patent as a limitation of the invention and in accord with an explicit definition for "preserving cells" in the specification.*** The preamble provides antecedent basis for the body of the claim, which recites "a sample collection reservoir having an opening configured to receive *the biological sample* from a user into the sample collection reservoir." The patent disclosure emphasizes the importance of preserving cells in collected samples of bodily fluids. The preamble of "collecting and preserving a biological sample" is consistent with that

significant feature of the invention. And the short phrase of the preamble is not suitable for parsing as Genotek urges, i.e., to read all but one word of the preamble (preserving) as limiting. Once the preamble is properly deemed to be a limitation of the claimed invention, its meaning is straightforward from the specification's repeated and consistent description of the significance of preserving cells in a sample and its explicit definition, namely "'preserving cells' means preventing cells from having their antigens degraded, such that they can be purified or enriched based on their antigens, and preventing alterations in the cellular epigenome." Appx180 (16:23-27).

ARGUMENT

I. GENOTEK'S APPEAL IS MOOT AS TO THE '187 PATENT

The district court granted summary judgment on the '187 patent because

> no reasonable jury could conclude that the accused products literally satisfied the "containment vessel having a top having an opening…said opening for receiving a liquid sample and for sealably receiving a cap" claim limitation based on the structure identified by Genotek.

Appx92. Genotek's appeal does not challenge that determination. Rather, Genotek challenges only the district court's construction of a different claim term—"reagent compartment." But the district court stated explicitly that its "entry of summary judgment of non-infringement is not based on the 'reagent compartment' limitation." Appx101. Indeed, the district court rejected Genotek's request for reconsideration of the "reagent compartment" construction as moot because, among other reasons, the court's grant of summary judgment of non-infringement was based on a different limitation—the "a containment vessel having a top having an opening" limitation. *Id.*

Because Genotek's appeal does not address the bases for the district court's judgment of non-infringement, the appeal necessarily fails. *See Acceleration Bay LLC v. 2K Sports, Inc.*, 15 F.4th 1069, 1077 (Fed. Cir. 2021) (appeal necessarily fails where an appellant challenges construction of one claim limitation but not a separate

claim limitation on which the district court's non-infringement judgment was based).[2]

Genotek argues it "does [not] matter that the district court said it granted summary judgment based on a different limitation—the purported absence of a 'containment vessel' in Spectrum's products." Br. at 38. Genotek alleges this is so because the district court, in granting summary judgment, "addressed Genotek's *amended* infringement contentions, which were changed in response to the district court's construction." *Id.* at 39 (italics in original). However, the district court did not, and could not, rely on infringement contentions when granting summary judgment. "Infringement contentions provide notice to the alleged infringer as to the patent owner's theory of infringement; they are not evidence for purposes of summary judgment." *Pulse Elecs., Inc. v. U.D. Elec. Corp.*, No. 18-CV-00373, 2021 WL 981123, at *23 (S.D. Cal. Mar. 16, 2021), *aff'd*, No. 2021-1856, 2022 WL 1436146 (Fed. Cir. May 6, 2022); *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242,

[2] Some circuits hold these circumstances warrant affirmance on the merits, rather than deeming the appeal moot. *See Sapuppo v. Allstate Floridian Ins. Co.*, 739 F.3d 678, 680 (11th Cir. 2014) (holding appellant who fails to appeal one of the grounds of judgment has "abandoned any challenge of that ground, and it follows that the judgment is due to be affirmed.").

(1986) ("[T]he plaintiff must present affirmative evidence in order to defeat a properly supported motion for summary judgment."); Fed. R. Civ. P. 56(c)(1)(A).

Thus, the district court evaluated, as it must, the evidence submitted by Genotek in opposing summary judgment, which included the expert declaration of Dr. Wereley. *See, e.g.*, Appx84-Appx87 (citing Appx3820, Appx4017). Dr. Wereley stated he understood the court's construction of "containment vessel" and applied it when opining that the accused products, with the tube and cap together, meet the "containment vessel" limitation. Appx4037. Based on Genotek's evidence and the admission of Genotek's counsel regarding the plain meaning of "top" (Appx88, Appx5783-84), the district court correctly held that no reasonable jury could conclude that the accused products meet the "containment vessel having a top having an opening…" limitation. Appx92, Appx97-98.

Because Genotek did not appeal the construction of the "containment vessel" limitation, nor the district court's grant of summary judgment based on that claim limitation, Genotek's appeal necessarily fails.

II. THE DISTRICT COURT CORRECTLY CONSTRUED "REAGENT COMPARTMENT" IN THE '187 PATENT

A. The '187 Patent Limits "the Invention" to Devices with the Reagent Compartment in the Container

The specification of the '187 patent describes the device of the invention as having a reagent compartment located in the container. The patent divides its invention into seven aspects. It is in the sixth aspect that the '187 patent describes the device of its invention. Here, as part of the Summary of the Invention, the '187 patent states that "the invention features a device" that includes the reagent compartment in the container:

> In a sixth aspect, ***the invention features a device*** for preserving and/or isolating a nucleic acid obtained from a biological sample. ***The device includes***: a container that has a first region for collecting a biological sample and ***a second region containing a composition for preserving a nucleic acid***, a barrier between the first region the second region….

Appx133 (6:26-36) (emphasis added). And, in the seventh aspect of the invention, the patent describes the method of manufacturing the device of the invention, again indicating it is a device with a reagent compartment in the container. Appx133 (6:46-56).

The Detailed Description likewise declares that, in addition to the invention's composition and methods, "[t]he invention also provides a novel collection device…," Appx137 (14:40), and here it uses the same language as the Summary of the Invention to state again that the reagent compartment of the device of the

invention is located in the container. Appx137 (14:51-58). These statements are not describing mere preferred embodiments, but the device of the invention *as a whole*. "When a patent thus describes the features of the 'present invention' as a whole, this description limits the scope of the invention." *Regents of Univ. of Minnesota v. AGA Med. Corp.*, 717 F.3d 929, 936 (Fed. Cir. 2013).

The holding in *Techtronic* is directly on point. There, the claims were silent as to the location of a passive infrared detector in the claimed garage door opener. *Techtronic Indus. Co. v. Int'l Trade Comm'n*, 944 F.3d 901, 904-905 (Fed. Cir. 2019). This Court determined that the patent, "by consistently representing the invention as the placement of the detector ***in the wall console***, has thus ***effected a disavowal of alternative locations***." *Id.* at 908 (emphasis added). Thus, the Court construed "wall console" to include the infrared detector. *Id.* at 910. Similarly, here the district court correctly concluded, "this language in the specification constitutes a clear disclaimer explaining that when the claimed invention is a sample collection device (as opposed to a composition or a method), the reagent compartment is ***in the container*** of the device and ***not in alternative locations***." Appx35-36 (emphasis added).

B. Genotek's Intentional Omission of the Provisional's Reagent Compartment-in-the-Cap Embodiment from the '187 Patent Supports the Disclaimer

The '187 patent claims priority to the '398 provisional. The '398 provisional describes a sample collection device having a reagent compartment. It describes one embodiment where the reagent compartment is in the cap of the device. This embodiment is shown in Figure 2 of the provisional (reproduced below).

FIGURE 2

Appx3190 (Figure 2); Appx3185 ("the [reagent] compartment is the underside of the cap"). The '398 provisional describes a different embodiment that includes the reagent compartment in the container. Appx3190 (Figs. 3-5).

When Genotek filed its non-provisional application, it intentionally deleted all references to the embodiment with the reagent compartment in the cap. This included Figure 2 and its associated description. Genotek included only the embodiments with the reagent compartment in the container in the '187 patent. In

the written description of the '187 patent, Genotek then limited the device of its invention to one having a reagent compartment in the container.

Although the '187 patent purports to incorporate by reference the '398 provisional application, "incorporation by reference does not convert the invention of the incorporated patent to the invention of the host patent." *Finjan LLC v. ESET, LLC*, 51 F.4th 1377, 1382 (Fed. Cir. 2022) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1553 (Fed. Cir. 1996)). "Rather, the disclosure of the host patent provides context to determine what impact, if any, a patent incorporated by reference will have on construction of the host patent claims." *Id.* (quoting *X2Y Attenuators, LLC v. U.S. Int'l Trade Comm'n*, 757 F.3d 1358, 1362-63 (Fed. Cir. 2014)). Here, the host '187 patent provides meaningful context by showing that Genotek intended the device of its invention to have the reagent compartment in the container. Indeed, Genotek purposely included only the embodiments with the reagent compartment in the container in the disclosure of the '187 patent and omitted reference to any device with a reagent compartment in the cap. In this context, incorporating the '398 provisional by reference does not impact the '187 patent's disclaimer of devices with a reagent compartment anywhere other than in the container. *Finjan,* 51 F.4th at 1382.

Furthermore, this Court has held that deletion of material from a provisional application directly affects claim construction. *MPHJ Tech. Invs., LLC v. Ricoh Americas Corp.*, 847 F.3d 1363, 1369 (Fed. Cir. 2017). In *MPHJ*, the patentee sought a narrow construction of a claim term to escape a validity challenge based on limiting statements in a provisional application. *MPHJ*, 847 F.3d at 1368. This Court rejected the patentee's argument because, like the '187 patent, that disclosure in the provisional application was omitted from the non-provisional in contrast to other portions of the provisional application, which were bodily incorporated. *Id.* This Court relied upon the patentee's deletion of the disclosure in construing the claims and held that "deletion from the [p]rovisional application [] contributes understanding of the intended scope of the final application." *Id*. at 1369.

Here, the district court correctly found that "the patentee's deletion of any explicit disclosure of the reagent compartment being in [] the cap/lid along with the disclaimers in the issued version of the specification explaining that the reagent compartment is in the container evidence a clear intent to limit the final scope of the invention to a device with the reagent compartment in the containment vessel." Appx39-40.

C. Genotek's Representations to the Public and the Patent Office that the Reagent Compartment of the '187 Patent is Limited to the Container Support the Disclaimer

Consistent with the statements of disclaimer in the '187 patent, Genotek also represented to the public and the Patent Office that the device of the '187 patent is limited to one with the reagent compartment located in the container.

In 2006, Genotek filed the '381 patent listing as an inventor the sole inventor of the '187 patent, Dr. Birnboim. Like the '187 patent, Genotek's '381 patent discloses a sample collection device with a reagent chamber for releasably storing a substance. However, as shown, for example, in annotated Figure 24 below, the '381 patent was specifically directed to a reagent compartment in the cap of the device.

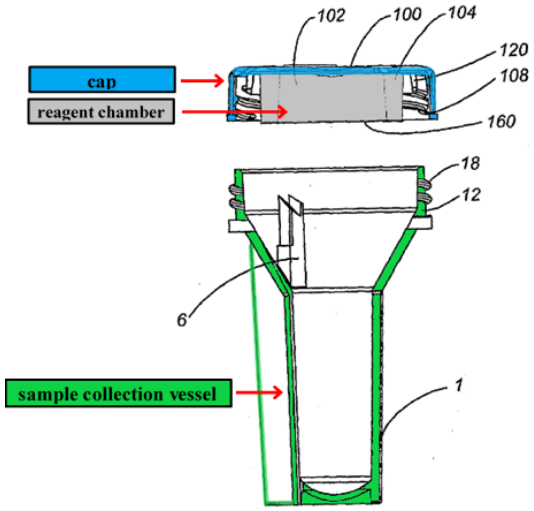


FIG. 24

Appx1586 (Fig. 24 (annotated)); *see also* Appx1587 (4:24-33).

The ’381 patent distinguished the earlier-priority ’187 patent by describing that disclosure as related to a device with a reagent compartment in the container: “This ***container has*** a first region for collecting a biological sample, ***a second region containing a composition for preserving nucleic acid***, and a barrier between the first region and a second region.” Appx1586 (1:50-59)[3] (emphasis added). Thus, Genotek distinguished the prior art ’187 patent from the ’381 patent, which was specifically directed to a reagent compartment in the cap. Appx1592 (13:1-2) (claim 1).

Later, in 2016, when the ’381 patent was challenged in an IPR based on the disclosure of the ’187 patent (referred to as “Birnboim” in the IPR), Genotek argued that the reagent compartment of the ’187 patent cannot be in the lid. The petitioner had argued, *inter alia*, that it would have been obvious to modify Birnboim with the O’Donovan reference to locate the reagent compartment in the lid. Genotek successfully opposed institution of the IPR, arguing: “Technically, O’Donovan and Birnboim are very different devices.” Appx1562. This is because O’Donovan “is a pushed friction fit engagement with spikes in a vial and ***a reagent in a lid***,” *id.*

[3] The ’381 patent uses the same description as the ’187 patent to explain that the reagent ’187 patent’s device includes the reagent compartment in the container.

(emphasis added), whereas the '187 patent has "a rotated screw cap with a ram in the cap and ***a reagent below a plastic cover in a container***…." Appx1563 (emphasis added).

The PTAB denied institution of the IPR. Appx1504-16. In so doing, the PTAB characterized the '187 patent, like Genotek, as having the reagent compartment in the container. Appx1510 (describing container in '187 patent as having a "sealing disc [that] divides the container into two regions," with the preservation composition in the second region below the sealing disc).

Spectrum has not asserted that Genotek's characterizations in the '381 patent and the IPR challenging the '381 patent constitute estoppel. Appx1205. Instead, Genotek's admissions are probative of Genotek's own understanding that the device invention of the '187 patent is limited to the reagent compartment in the container. Indeed, this Court has explained that "[w]e take the patentee at its word and will not construe the scope of [] claims more broadly than the patentee itself clearly envisioned." *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004).

Relying on multiple precedents from this Court, the district court agreed that Genotek's admissions should be appropriately considered in claim construction:

> [T]he statements at issue are not mere statements made in an unrelated application. Rather, they are statements by the patentee about the scope

> of its own invention in an official proceeding, represented by counsel, in an effort to preserve the validity of another one of its patents. There are many good reasons why these statements are and should be relevant for claim construction purposes.

Appx41-42 (internal quotations omitted) (citing *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004); *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006)).

Admissions are, of course, relevant evidence, and courts have long recognized the relevance of statements by inventors and patentees in characterizing their own invention. *See Jungersen v. Baden*, 166 F.2d 807, 809 (2d Cir. 1948), *aff'd sub nom. Jungersen v. Ostby & Barton Co.*, 335 U.S. 560 (1949) (stating "[t]he inventor's appraisal of his own invention is of course of importance" when evaluating scope of inventor's U.S. patent in view of his characterization of same subject matter in British patent); *Morse v. United States*, 78 Ct. Cl. 608, 632 (1934) *cert. denied*, 292 U.S. 652 (1934) (finding patentee's characterization of claim scope in a separate lawsuit to be an "admission against his interest we think is entitled to much weight"). Moreover, the significance of a patentee's statements characterizing its invention is "enhanced by the fact that [they were] made in an official proceeding in which the patentee had every incentive to exercise care in characterizing the scope of its invention." *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1312-13 (Fed. Cir. 2014), *overruled on other grounds by Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed.

Cir. 2015) (quoting *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004)). Genotek should be taken at its word that the reagent compartment of the device invention in the '187 patent is limited to the container.

D. Genotek Shows No Error in the District Court's Construction of "Reagent Compartment"

1. The district court's finding of disclaimer is consistent with this Court's precedent

Genotek does not dispute, nor can it, that it repeatedly described the device of its invention in the '187 patent as a device having the reagent compartment in the container. Instead, Genotek challenges this Court's precedent on the law of disclaimer. Genotek argues for a heightened standard to support a showing of disclaimer, asserting that "without more" the clear and express statements in the '187 patent describing the device of its invention "fail[] to justify" the district court's construction of "reagent compartment." Br. at 30-31.[4] For example, Genotek suggests that the specification must discuss the "importance, essentiality, or

[4] Genotek also alleges that the district court ignored the standard for disclaimer. Br. at 28. Not so. The district court issued a thorough claim construction order, providing a detailed recitation of the legal standard for claim construction, and faithfully applied it, point by point, to find that Genotek clearly and expressly disclaimed devices with a reagent compartment anywhere other than in the container. Appx31-44.

criticality" of a feature, or dictate what the feature "is or does" before a description of that feature as the present invention can limit the scope of the claims to that feature. *Id.* at 29-30. That is not the law.

This Court's precedent holds that an inventor's statements are dispositive where the inventor has manifested intention that the invention does or does not include a particular aspect:

> Claim terms are normally given their ordinary and customary meaning, as understood by persons of ordinary skill in the art in view of the specification and prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). But ***where the inventor*** has clearly set forth a different definition of a claim term, or ***has manifested that the invention does*** or does not ***include a particular aspect, that intention "is regarded as dispositive."*** *Id.* at 1316 (citing *SciMed Life Sys., Inc. v. Adv. Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343–44 (Fed. Cir. 2001)).

Techtronic, 944 F.3d at 907 (emphasis added). In the '187 patent, Genotek manifested its intention "that the invention does…include a particular aspect," *id.*, specifically that the device includes the reagent compartment located in the container. Appx133 (6:26-36) (describing invention's "sixth aspect"); Appx137 (14:40, 14:51-58). Nothing more is required where, as here, the patentee clearly manifested its intention in the specification.[5] *Techtronic*, 944 F.3d at 907.

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[5] Still, as discussed herein, the district court also correctly found that additional evidence supports the finding of Genotek's disclaimer. *See* Appx38-44.

The cases cited by Genotek do not support any other conclusion. Genotek relies on *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353 (Fed. Cir. 2016) to assert that "even when the patent uses the phrase 'the present invention' or similar phrases," "this Court has rejected attempts to narrow claim terms to specific embodiments." Br. at 29. The holding in *Unwired Planet* is not so broad. *Unwired Planet*, 829 F.3d at 1358 ("Every claim construction, and each potential disclaimer, has to be considered in the context of each individual patent."). There, the district court construed the term in question to be limiting based on its use in a paragraph in the specification that begins with "[t]he present invention." *Id.* at 1356. However, the allegedly limiting term was discussed only later in the paragraph, not in connection with the phrase "the present invention." *Id.* at 1358 ("[T]his first sentence does not even mention a voice communication channel."). Further, other claims recited the term "voice communication channel," signifying that the patentee could have, if intended, included the same term in the claims-at-issue. *Id.* at 1358-1359. Thus, this Court rejected the limiting construction because the phrase "the present invention" did not manifest any intent to limit the claim in the particular manner at issue. By contrast, Genotek clearly and expressly stated its intent in the '187 patent that the device of the invention is a device with the reagent compartment in the container.

Genotek cites to *Hill-Rom* to argue that this Court's precedent requires a patentee to do more than manifest its intent. Br. at 29-30. *Hill-Rom* does not impose a heightened standard for disavowal. Indeed, this Court in *Hill-Rom* rejected the district court's restrictive construction of the term "datalink" precisely because "[t]here are no words of manifest exclusion or restriction" in the specification. *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014). This Court observed that, unlike here, "[t]here is no disclosure that, for example, the present invention 'is,' 'includes,' or 'refers to' a wired datalink." *Id.*

In *Hill-Rom*, this Court also rejected a restrictive construction of a different term that did use the phrase "the present invention." *Id.* at 1375-77. But it did so because the specification described it as only "one embodiment…'in accordance with the present invention'" and, moreover, a different embodiment in the specification contradicted the district court's limiting construction. *Id.* at 1377. Although this Court referred to the absence in the specification of a "discussion of the importance, essentiality, or criticality" of the feature in question, *id.*, the Court did not establish it as a new standard for disclaimer of claim scope. The Court was determining whether the specification included such language as an independent basis for finding disclaimer. *See, e.g., id.* at 1372 (indicating separate bases for

disclaimer can include patentee describing "the present invention," describing a step as "required," or describing a feature as "very important").

Continental Circuits also does not support the heightened standard that Genotek seeks to impose for finding disclaimer. Although the specification used the phrase "the present invention," it was not used to describe the invention "as a whole." *Cont'l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 798 (Fed. Cir. 2019). Further, the phrase was used alongside other non-limiting language such as "one technique," "can be carried out," and "a way" to describe the present invention. *Id.* at 797-798.

Genotek's reliance on *Rambus* is similarly misplaced. Genotek contends that "the district court was not 'clarify[ing] or constru[ing] the actual words of the claim'; it was creating an additional claim requirement." Br. at 30 (quoting *Rambus Inc. v. Infineon Techs. Ag*, 318 F.3d 1081, 1089 (Fed. Cir. 2003) (alterations by Genotek). However, *Rambus* addresses prosecution history disclaimer, not disclaimer in the specification. *Rambus*, 318 F.3d at 1090 (rejecting the district court's finding of prosecution history disclaimer). There, the Court rejected the district court's limiting construction because the district court improperly relied on a "facially inaccurate remark during prosecution." *Id. Rambus* has no bearing to this case.

Genotek also attempts to distinguish the cases the district court relied on in reaching its construction. Br. at 31-32. Genotek focuses on *Techtronic*, arguing it

requires that the specification describe the feature in question as "'the critical and inventive feature' over the prior art." Br. at 31 (quoting *Techtronic*, 944 F.3d at 910). But that is not law. That the specification in that case may have so described the feature in question (passive infrared detector) does not make such a distinction a requirement for finding a disavowal. *Techtronic* does not suggest otherwise.

Indeed, *Techtronic* establishes that the patentee's intention "is regarded as dispositive" where, as here, the patent specification includes a clear limiting description of the invention. *Techtronic*, 944 F.3d at 907. Further, the Court admonished the lower tribunal for imposing a heightened standard for disavowal such as what Genotek now seeks to impose. *Id.* at 909 (Where the specification represents "the scope of the invention to the exclusion of some embodiments, it is unnecessary that it also concede that those embodiments are 'infeasible' or even 'impossible' by reference to its teachings."); *id.* ("[T]here is also no requirement that the prosecution history reiterate the specification's disavowal."). In a footnote, Genotek attempts to distinguish the remaining cases cited by the district court. Br. at 32, n.6. But these characterizations are equally unavailing in supporting Genotek's argument.

Genotek also cites boilerplate language in the '187 patent in an attempt to recapture the disavowed claim scope. Br. at 26 (citing Appx134 (7:65-8:3)).

However, "such boilerplate language, without more, is not sufficient to overcome the explicit description of the 'present invention.'" *SandBox Logistics LLC v. Proppant Express Invs. LLC*, 813 F. App'x 548, 554 (Fed. Cir. 2020) (citing *D Three Enters., LLC v. SunModo Corp.*, 890 F.3d 1042, 1051 (Fed. Cir. 2018) ("[B]oilerplate language at the end of the…specification is not sufficient to show adequate disclosure of the actual combinations and attachments used in the...[c]laims.")).

The cited boilerplate language is particularly off point here because it only purports to apply to the "detailed description and the specific examples." Appx134 (7:65-8:3). This necessarily excludes the Summary of the Invention where the patentee declared "the invention features a device" having a reagent compartment located in the container. Appx133 (6:26-32).

Genotek cites *Pfizer* to argue boilerplate language can be used to recapture disclaimed claim scope. Br. 26 (citing *Pfizer, Inc. v. Ranbaxy Lab'ys Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006). But *Pfizer* is distinguishable on its face. There, the patent examples were directed to manufacturing racemates of a compound and the issue was whether the claims were thus limited to racemates, rather than including enantiomers as otherwise permitted by the claim language. *Pfizer*, 457 F.3d at 1290. Relying in part on language concerning the scope of the examples, the Court found no express intention that the patent examples were meant to be "strictly co-

extensive" with the claims. *Id.* at 1290 (quoting *Phillips*, 415 F.3d at 1323). Notably, the Court recognized that the patentee had, elsewhere in the specification, clearly and expressly disclaimed claim scope to cis isomers, *id.* at 1289, and the patent's boilerplate language did not obviate this express disclaimer. Here too, boilerplate language in the '187 patent cannot obviate Genotek's clear and express statements that the device of the invention has the reagent compartment located in the container.

2. The district court properly relied on Genotek's omission of the reagent compartment-in-the-cap embodiment from the '187 patent

Genotek intentionally omitted from the disclosure of the '187 patent all references from the '398 provisional describing a device with the reagent compartment in the cap. But Genotek contends that this omission is not relevant to whether the reagent compartment of the device invention of the '187 patent is limited to the container. *See* Br. at 32-34. Genotek goes further and characterizes the district court's reasoning as "backwards," arguing that, in fact, "there was no omission" due to the '187 patent's incorporation by reference of the '398 provisional. Br. at 32. Genotek's argument lacks merit.

Genotek does not, and indeed cannot, dispute that it bodily incorporated into the '187 patent the embodiment in the '398 provisional showing a reagent compartment in the container, including faithful reproductions of the relevant figures. Further, there is no dispute that Genotek excluded from the '187 patent the

embodiments in the ’398 provisional showing a reagent compartment in the cap. As this Court stated in *Finjan*, “the disclosure of the host patent provides context to determine what impact, if any, a patent incorporated by reference will have on construction of the host patent claims.” *Finjan*, 51 F.4th at 1382 (quoting *X2Y Attenuators,* 757 F.3d at 1362-63). Here, Genotek manifested its intention to limit the scope of the claimed device to one having the reagent compartment located in the container. Accordingly, Genotek disavowed any contrary embodiments, *including* any embodiments in the ’398 provisional having the reagent compartment in the cap, even though the ’187 patent included a statement incorporating by reference the ’398 provisional. *Id.* (“[I]ncorporation by reference does not convert the invention of the incorporated patent to the invention of the host patent.”) (quoting *Modine*, 75 F.3d at 1553); *id.* at 1383 (“The use of a restrictive term in an earlier application does not reinstate that term in a later patent that purposely deletes the term, even if the earlier patent is incorporated by reference.”).

But the ’187 patent fails to even properly incorporate by reference the ’398 provisional application. Under 37 C.F.R. § 1.57(d), the ’187 patent cannot incorporate by reference the ’398 provisional application: “‘Essential material’ may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication.” 37 C.F.R. § 1.57(d). The ’398

provisional is not a "U.S. patent or U.S. patent application publication." Thus, Rule 1.57(d) applies here based on its plain language.

Consistent with the rule's plain language, the PTAB and at least one district court have concluded that Rule 1.57(d) renders incorporation by reference of a provisional application ineffective. In *ZTE (USA) Inc. v. Cywee Grp. Ltd*., the PTAB held that under Rule 1.57(d), "a U.S. provisional application is not a 'U.S. patent or U.S. patent application publication,' [and that] the [patent's] incorporation by reference of the [] provisional application was ineffective as to the [deleted] embodiment." 2021 WL 641742, at *54 (P.T.A.B. Feb. 17, 2021). The district court in *Nomadix, Inc. v. Second Rule LLC* held that if Rule 1.57 applied to the challenged patent, "there would be no question that the [] provisional application was improperly incorporated." 2009 WL 10668158, at *24 (C.D. Cal. Jan. 16, 2009). In *Nomadix*, the court held that Rule 1.57 did not apply only because the application that issued as the challenged patent was filed in October 2000 and Rule 1.57 became effective in October 2004. *Id.* Here, on the other hand, the application that issued as the '187 patent was filed in 2016, twelve years after enactment of Rule 1.57.

Here, the district court declined to rely on Rule 1.57(d) (and also found it unnecessary to do so) in its construction of "reagent compartment." *See* Appx36, n.16. The district court explained it was not bound by the decisions in *ZTE* and

Nomadix and it was compelled to follow this Court's statement in *Trustees of Columbia University* that "provisional applications incorporated by reference are effectively part of the specification as though it was explicitly contained therein." Appx36 (quoting *Trs. Of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1366 (Fed. Cir. 2016) (internal quotation marks omitted). But in that case, the issue of Rule 1.57(d) was not before this Court. Indeed, the district court acknowledged that *Trustees of Columbia University* did not address Rule 1.57(d), but nevertheless relied on statements in that case regarding incorporation by reference of a provisional application. Appx36, n.16. Although not necessary in affirming the district court's construction, this Court may now consider the effect of Rule 1.57(d) and, if it does so, should hold that it bars Genotek from relying on the '187 patent's statement of incorporation by reference to the '398 provisional for "essential material," including the reagent compartment-in-the-cap embodiment that Genotek intentionally omitted from the '187 patent.

3. The district court properly relied on Genotek's representations in the '381 patent specification and in the IPR

In the specification of the later-priority '381 patent, Genotek represented to the public that the device disclosed in the '187 patent has its reagent compartment located in the container. Appx1586 (1:50-59). Spectrum cited to this disclosure in its claim construction briefing, and the district relied on it as evidence of how

Genotek itself understands the scope of its invention in the '187 patent. *See* Appx1204; Appx41 (citing Appx1586 (1:50-59)). On this issue, Genotek is silent, having failed to acknowledge, let alone address, this admission in the '381 patent about the scope of its invention in the '187 patent.

With respect to the representations Genotek made about the '187 patent in the IPR challenging the '381 patent, Genotek attempts to minimize these statements as made "during an IPR of an unrelated patent." Br. at 34-35. Genotek's argument is without merit. Genotek analogizes the situation here to cases where a litigant has attempted to use a patentee's statements made during prosecution of a first patent to construe claim terms in a second unrelated patent. *See* Br. at 35 (citing *Pfizer*, 457 F.3d at 1290; *Apple*, 757 F.3d at 1312; *Hill-Rom*, 755 F.3d at 1381). This situation is entirely different: Genotek made statements *about the '187 patent* that are directly relevant to the scope of the claims *in the '187 patent*. The district court relied on Genotek's statements as evidence of how Genotek itself understands the scope of that same invention in the '187 patent—not in some other unrelated patent. As the district court aptly stated, "the statements at issue are not mere statements made in an unrelated application. Rather, they are statements by the patentee about the scope of its own invention in an official proceeding, represented by counsel, in an effort to preserve the validity of another one of its patents." Appx42.

The Court should not disregard these representations, as Genotek urges, simply because they were made during Genotek's defense of an unrelated patent where the '187 patent was used as prior art. A competitor like Spectrum should be "entitled to rely on [Genotek's] representations when determining a course of lawful conduct, such as launching a new product or de-signing-around a patented invention.'" *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1359 (Fed. Cir. 2017).

Genotek also attempts to minimize its representations about the '187 patent during the '381 patent's IPR by cabining the statements to a "preferred embodiment." Br. at 36-37. This argument is unavailing for at least three reasons. *First*, the '187 patent discloses just one device of its invention—the device with the reagent compartment in the container—thus, labeling it the "preferred embodiment" does not have any bearing on the effect of Genotek's representations during the IPR.

Second, Genotek's argument ignores that the petitioner's obviousness challenge was based on the disclosure of the '187 patent, not any single embodiment. An obviousness determination requires an analysis of the scope and content of the prior art. Thus, as the district court explained, "the scope of the teachings in Birnboim (i.e., the scope of its disclosure) was directly at issue during the relevant IPR proceedings and in the statements made by DNA Genotek." Appx43 (citing

Polaris Indus., Inc. v. Arctic Cat, Inc., 882 F.3d 1056, 1069 (Fed. Cir. 2018) (internal alterations and quotations omitted).

Third, Genotek's argument is belied by its own detailed explanation of the '187 patent device in the IPR briefing. *See* Appx1555-57. The petitioner had argued that the '187 patent's discussion of a septum or plastic bag alternative is "incomplete" and therefore suitable for modification with the O'Donovan reference, which has its reagent compartment in the cap. Appx1555. Genotek disagreed, explaining that the septum and plastic bag are simply "alternatives for separating the sample and the composition" in the container. Appx1556. According to Genotek, it is all the same device, just replacing the plastic cover at the bottom of the vial with a septum. Appx1557 (Genotek asserting, based on a "plain reading" of the '187 patent, that septum is "at the bottom of the vial"). To avoid any ambiguity, Genotek again confirmed that the '187 patent's device includes a reagent compartment only in the container: "[W]hen Birnboim replaces the plastic cover with a septum, ***the only other change*** is to ensure the bottom of the push rod can pierce the septum." *Id.* (emphasis added).

In sum, the district court correctly construed "reagent compartment" and this Court should affirm the summary judgment of non-infringement of the '187 patent.

III. THE DISTRICT COURT CORRECTLY CONSTRUED "PRESERVING A BIOLOGICAL SAMPLE" IN THE '646 PATENT

A. The Court Correctly Held the Preamble Limiting

Genotek argues the preamble here is nothing more than an "intended use." Br. at 40-41. But the preamble does not merely state a purpose or intended use. It provides the antecedent basis for "the biological sample" recited in the body of the claim: "a sample collection reservoir having an opening configured to receive *the biological sample* from a user into the sample collection reservoir." Appx183 (claim 1). When a claim relies on a "preamble phrase for antecedent basis" it is a "'strong indication' that the preamble acts 'as a necessary component of the claimed invention.'" *Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1371 (Fed. Cir. 2020) (quoting *Eaton Corp. v. Rockwell Int'l Corp*., 323 F.3d 1332, 1339 (Fed. Cir. 2003)).

That is particularly true here because the preamble matches what the inventors disclosed as their invention. The claimed invention is a "kit for collecting and preserving a biological sample." Appx183 (claim 1). As set forth in the Abstract, the '646 patent's "disclosure relates to devices, solutions, and methods for collecting and processing samples of bodily fluids containing cells…." Appx142. The '646 patent does mention non-biological samples, for example "toxic and/or hazardous substances/fluids." *Id.* But when it comes to biological samples, the '646 patent

makes clear that it is referring to cells and the disclosed device preserves those cells. *See, e.g.*, Appx173-181 (1:20-30, 2:34-4:49, 4:53-61, 5:15-20, 5:21-25, 6:6-8:24, 9:44-10:15, 13:29-47, 14:54-15:5, 16:9-47, 16:62-17:42, 17:43-18:59, and 18:64-19:40).

The specification makes clear the inventors perceived the preservation of cells as a critical aspect of the invention. Starting with the Abstract the inventors informed the reader that the '646 patent's "disclosure generally relates to … the isolation and ***preservation of cells*** from saliva and other bodily fluids." Appx142 (emphasis added). And the rest of the specification repeatedly references cells and their preservation thereby confirming the inventors' initial statement from the Abstract. Given the specification's view that the invention was collecting and preserving cells, the inventors included that language when drafting the claims for "[a] kit for collecting and preserving biological samples." Appx383 (claim 1). The inventors then referred back to that same "biological sample" that is collected and preserved when reciting the "reservoir having an opening configured to receive the biological sample from a user into the sample collection reservoir." Appx383 (claim 1).

The district court correctly recognized the link between the preamble, the claims, and the patent's disclosure, observing: "Whether to treat a preamble as a limitation is a determination 'resolved only on review of the entire[] . . . patent to

gain an understanding of what the inventors actually invented and intended to encompass by the claim.'" Appx60 (quoting *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc*., 289 F.3d 801, 808 (Fed. Cir. 2002)) (alterations in original). The district court noted that this Court "has recognized certain 'guideposts' for making that determination" and that "[o]ne of those guideposts is that: 'When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention.'" *Id*. (quoting *Eaton*, 323 F.3d at 1332).

By referring back to the biological sample of the preamble, the '646 patent links the claimed structure, including "a sample collection reservoir having an opening configured to receive *the biological sample* from a user into the sample collection reservoir," to the preamble's requirements, namely a biological sample that is collected and preserved. The preamble thus provides "an important characteristic of the claimed invention." *Poly-America, LP v. GSE Lining Tech., Inc*., 383 F.3d 1303, 1310 (Fed. Cir. 2004).

Genotek initially ignores the antecedent basis provided by the preamble. Instead, Genotek argues that the claim defines a structurally complete invention, with the preamble nothing more than an intended purpose. Br. at 40-41. Genotek relies on cases like *Arctic Cat Inc. v. GEP Power Prods., Inc*., 919 F.3d 1320, 1328

(Fed. Cir. 2019), which it calls "instructive." Br. 41. But *Arctic Cat* dealt with a different situation, with the Court explaining that the preamble in *Arctic Cat* did not "supply 'antecedent basis' for terms in the body…." *Arctic Cat*, 919 F.3d at 1329. In *Arctic Cat*, the absence of any antecedent basis in the preamble was "telling," and the preamble was held not limiting. *Id*.

Genotek also asserts that the specification's repeated discussion of preserving cells "relate to embodiments not claimed by the '646 patent." Br. at 43. Genotek then argues "[i]t is well-settled" that claims need not cover all disclosed embodiments. Br. at 43 (citing cases). But this is not an instance where the claim is silent about preserving the sample. Instead, the claim recites "collecting and preserving a biological sample," and then refers back to "*the* biological sample," i.e., that which is collected and preserved, when defining the claimed kit in the body of the claim.

Once Genotek does turn to the antecedent basis, its analysis skips over the importance of the preamble to the claimed invention. Genotek argues that the district court's construction "located antecedent language but never asked whether that language—'a biological sample'—defined any part of the invention." Br. at 45. Genotek further asserts the preamble's use of "a biological sample" does not "define[] or explain[] what that biological sample is" and that the "none of the

claimed apparatus's structures…depends on how the preamble describes 'a biological sample.'" Br. at 45. But the claims do recite structure related to the collection and preservation of a biological sample — the claims recite the structure of the device for receipt of the biological sample (the sample collection reservoir) and the valve structure that provides for mixing between the reagent chamber and the sample collection reservoir, which receives and stores the biological sample.

Genotek's argument that the claims are directed to an apparatus disconnected from the requirement of collecting and preserving a biological sample is also belied by how Genotek defined a person of ordinary skill in the art. Per Genotek's expert, "The Asserted Patents contain both chemical and mechanical aspects.… I have only provided my opinion with respect to the chemical aspects of the claimed inventions of the Asserted Patents." Appx2829 (¶ 38). According to the expert, a person of ordinary skill in the art "would have been knowledgeable and familiar with the preservation of biological samples and nucleic acid" and would have had education and experience relating to the same. *Id.* But if the preamble of the '646 patent claims were not limiting, as Genotek argues, there would be no biological or chemical aspects of the claimed invention.

Genotek's arguments against reading the preamble to define the claimed invention further relies on parsing the preamble into separate parts and ignoring the

linked requirements for collecting and preserving the biological sample. Br. at 45-46. The preamble here "cannot be neatly packaged into two separate portions," so Genotek's approach of "splicing" the preamble into different pieces and separating out the parts it does not like is disfavored. *Bio-Rad*, 967 F.3d at 1371. Genotek argues that "some preamble language is limiting does not imply that other preamble language, or the entire preamble, is limiting." Br. at 46 (*quoting Cochlear Bone Anchored Sols. AB v. Oticon Med. AB*, 958 F.3d 1348, 1355 (Fed. Cir. 2020)). But unlike *Cochlear Bone*, the preamble here links "collecting and preserving" to the "biological sample"—the same term used in the claim.

Moreover, Genotek solely disputes the limitation provided by the word "preserving," in the preamble, but raises no such concerns about the remainder of the preamble that recites "collecting…a biological sample." *See, e.g.*, Br. at 46-47. Thus, unlike *Cochlear Bone* and other cases, Genotek suggests excising a single word—"preserving"—from the preamble while keeping the rest. *Bio-Rad* rejected this approach. *Bio-Rad*, 967 F.3d at 1371.

Genotek attempts to distinguish *Bio-Rad* because it "was for a *method*" in contrast to '646 patent's claims "directed only to an apparatus." Br. at 47. But *Bio-Rad*'s reasoning is equally applicable here because the term providing antecedent

basis cannot be read separately from the remainder of the preamble. *Bio-Rad*, 967 F.3d at 1371.

This is not a situation where the preamble can be parsed into pieces as Genotek urges, i.e., essentially striking a portion to read "collecting ~~and preserving~~ a biological sample." The short preamble identifies and links two requirements: "collecting and preserving a biological sample." Appx183. If a preamble "cannot be neatly packaged into two separate portions," then "splicing" is disfavored. *Bio-Rad*, 967 F.3d at 1371. In this instance, the preamble cannot be separated into pieces. Instead, as set forth in the specification, there is an intimate relationship between collecting and preserving a biological sample. Appx173 (1:19-30). Accordingly, and consistent with the claim language and specification, the district court correctly construed the entire preamble as limiting.

B. The District Court Correctly Construed the Preamble

The district court construed "preserving a biological sample" as "preventing cells in the biological sample from having their antigens degraded such that they can be purified or enriched based on their antigens, and preventing alterations in the cellular epigenome." Appx65. The court applied a two-step analysis. First, the court noted that it had already construed the term "biological sample" as a "biological sample containing cells." *See* Appx62 (citing prior construction,

Appx57-59). Second, based on its prior construction for "biological sample," the court applied the specification's disclosure and express definition for "preserving cells." Appx64-65 (citing Appx180 (16:23-27)).

The court's well-reasoned analysis correctly construed "preserving a biological sample." That construction, and the attendant grant of summary judgment, should be affirmed.

1. The district court correctly held "preserving a biological sample" requires preserving cells in a biological sample

The '646 patent, from its start, makes clear that the invention "relates to devices, solutions and methods for collecting and processing samples of bodily fluids containing cells…." Appx142 (Abstract). The patent likewise narrows the "Field of the Disclosure" to (1) "devices, solutions and methods for collecting samples of bodily fluids or other substances" and (2) "to the isolation and preservation of cells from such bodily fluids." Appx173 (1:19-30).

Such statements define the inventors' understanding as to the scope of the invention. *Regents of Univ. of Minnesota v. AGA Med. Corp*., 717 F.3d 929, 936 (Fed. Cir. 2013). When a patent describes the features of the present invention as a whole, that description limits the scope of the invention. *Verizon Servs. Corp. v. Vonage Holdings Corp*., 503 F.3d 1295, 1308 (Fed. Cir. 2007). The '646 patent's characterization of the scope of "the disclosure," like the characterization of "the

invention" in *Verizon* and *Regents*, provides the context for understanding the invention as a whole. This is because "[t]he specification shall contain a written description of the invention," 35 U.S.C. § 112, so defining the limits of the disclosure necessarily defines the limits of the invention as well.

The remainder of the specification confirms that the scope of the '646 patent's disclosure, with respect to preserving bodily fluids, requires preserving cells. Among other things, the patent discusses in the "Summary of the Disclosure":

- the collection of bodily fluids and "preserving cells of samples collected," "isolating specific cells either collected and/or preserved," and analyzing "[s]uch isolated cells" in the "Summary of the Disclosure" (Appx174 (4:53-61))
- "preserving the antigenicity and epigenome of cells, and isolating rare cells" (Appx175 (6:49-53))
- "a solution for preserving cells in bodily fluids" (Appx175 (6:61-62))
- "a method for preserving cells in one or more bodily fluids" (Appx176 (7:7-11))

Statements regarding the scope of the disclosed invention do not always describe the invention as a whole. But here, the '646 patent's disclosure reinforces the statements defining the scope of the disclosure by repeatedly stating that the

"preserving" the patent is directed to is preserving the cells in the sample. In contrast, the "Summary of the Disclosure" does not mention preserving anything other than cells from a biological sample. And it is well settled that the specification, is "the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315.

The district court considered the claim language and specification and found that "the specification's use of the phrases 'the present disclosure' and 'the disclosure' alerts the reader that invention disclosed in the '646 Patent is directed to the preservation of cells in samples." Appx64. The district court further found that "the specification never references any type of preservation other than the preservation of cells." Appx64. Given the inventors' written description of the invention, and the court's construction of "biological sample," the court applied the '646 patent's definition of "preserving cells" to the claimed "preserving a biological sample." Appx64-65. There was no error in the court's analysis or construction.

On appeal, Genotek attempts to make much of a difference in terminology between the claims and the specification. The claims, which were filed in a continuation application years after the priority date of the '646 patent, use the term "preserving a biological sample," but as Genotek argues, the specification "never uses the phrase 'preserving a biological sample' at all." Br. at 49. Indeed, the

specification never uses even "biological sample." Genotek essentially relies on the *absence* of supporting evidence as demonstrating a broader invention. This Court should not countenance Genotek's arguments to sidestep the specification's disclosure to somehow claim a different invention than what is described in the patent.

That the specification never mentions a "biological sample," and instead discusses "bodily fluids containing cells," does not broaden the scope of the disclosure or justify changing the invention of that disclosure. *See, e.g.*, *GPNE Corp. v. Apple, Inc.*, 830 F.3d. 1365, 1368-71 (Fed. Cir. 2016) (affirming construction of "a node" as "a pager" where, apart from Abstract, the specification did not use "node," but repeatedly used "pager" and "paging units' consistently throughout).

Genotek also asserts the specification's disclosure mentions preserving cells in the context of "*solutions* and *methods*—not the kit that the patent here claims." Br. at 49. Not so. Consistent with the claim language, the '646 patent also limits its disclosure to "devices…for collecting samples of bodily fluids" and the "isolation and preservation ***from such bodily fluids***." Appx173 (1:19-30) ("Field of the Disclosure") (emphasis added). Genotek also suggests that the patent's disclosure "relevant to what the '646 patent claims…discusses the collection of bodily fluids,

not just cells." Br. at 50 (citing Appx174 (4:53-55); Appx175 (6:6-8)). But Genotek's first citations stop mid-sentence and omits the part that indicates the "preserving" is for "cells of samples collected" and that any analysis is carried out on "specific cells either collected and/or preserved." Appx174 (4:53-61). The second citation refers to a "bodily fluid sample," but that does not broaden the inventors' initial indication that the scope of the disclosure was a biological fluid containing cells. *See, e.g.*, Appx142 (Abstract); Appx173 ("Field of the Disclosure").

Despite the patent's clear statement of scope evident from the ubiquitous references to preserving cells and its explicit definition of what preserving cells means, Genotek goes so far as to argue the patent is directed to *cell-free* samples. Br. at 50 (citing Appx2837). Specifically, Genotek cites to expert testimony it offered on claim construction where the expert opined that "[o]ne of ordinary skill in the art would have known a biological sample of the '646 Patent is a *cell-free plasma sample* that contains either cell-free fetal DNA…obtained from the blood of a pregnant mother or cell-free circulating tumor DNA obtained from the blood of a cancer patient." Appx2837 (emphasis in original). Genotek's assertion on appeal that "Spectrum never contested these statements," Br. at 50, is incorrect. Spectrum

both objected to the testimony and explained why it should be rejected.[6] Not surprisingly, the expert declaration cited nothing in the patent for this cell-free contention. The patent says no such thing. The '646 patent has nothing to do with collecting and preserving cell-free blood plasma. Cell-free blood plasma is not something collected in a sample collection device such as described in the patent. Cell-free blood plasma could be a product that a scientist working in a laboratory could obtain after processing a sample that had been collected from a user, which sample originally contained cells. Genotek's argument that the patent is directed to cell-free blood plasma samples is also belied by the language of the claims—the claims say the biological sample is "from a user," not something obtained from a laboratory separation process. Appx183 (22:21).

Given the '646 patent makes no mention of collecting and preserving cell-free samples and this Court's guidance that "conclusory, unsupported assertions by

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[6] Spectrum objected to, and moved to exclude, this and other portions of the expert testimony based on Genotek's failure to provide the required notice under the Local Rules. *See* Appx2366-72. Spectrum also explained why the district court should not credit such unsupported expert testimony that contradicts the patent. Appx2358-59. The district stated that it was skeptical whether the declaration complied with the Local Rules, but declined to address the objections because it deemed the testimony immaterial and did not rely upon it. Appx6-7.

experts as to the definition of a claim term are not useful to a court," *Phillips*, 415 F.3d at 1318, the district court rightly did not rely upon the proffered testimony.

2. The intrinsic evidence supports the court's construction of "preserving a biological sample"

Genotek next argues that the court erred by applying the '646 patent's definition of "preserving cells" to the claimed "preserving a biological sample." Br. at 50-51. Genotek first asserts the specification's indication that the disclosure "relates generally…to the isolation and preservation of cells from such bodily fluids" does not indicate "that preserving cells is an essential feature of the claimed apparatus." Br. at 51. But the specification specifically links the collection of bodily fluids and the "preservation of cells from ***such*** bodily fluids." Appx173 (1:21-29) (emphasis added). Thus, unlike the cases Genotek cites, the specification here does limit its disclosure with respect to the claim's recitation of "collecting and preserving a biological sample." And, with respect to preserving the biological sample, the specification limits its disclosure to collecting and preserving biological samples that contain cells. Appx173 (1:21-29). Genotek's cited authority recognizes that such statements defining the scope of invention constitute disavowal. *See, e.g., Unwired Planet*, 829 F.3d at 1358 ("We have held statements such as 'the present invention includes...,' 'the present invention is ...,' and 'all embodiments of the present

invention are ...' to be clear and unmistakable statements constituting disavowal or disclaimer.").

The district court correctly recognized that "biological sample" in the body of the claim meant a "biological sample containing cells." Appx57-59. And the court recognized there was an express definition for "preserving cells" that applied to the claim language. Appx64-65. That definition of "preserving cells" is "preventing the cells from having their antigens degraded, such that they can be purified or enriched based on their antigens, and preventing alterations in the cellular epigenome." Appx180 (16:23-27). The Court's construction tracks this definition, and is consistent with the inventors' indication of the specification's limited scope. Appx65.

Genotek further argues that the grant of summary judgment "exposes the problems" with the district court's approach because "the district court identified no structural difference between Spectrum's products and the claimed apparatus." Br. at 52. But the Court's construction did not turn the apparatus claims into method claims, as Genotek alleges. Instead, the Court's construction gave life to the claim and properly limited it to the scope identified by the inventors by requiring the claimed kit must be configured to preserve cells.

In rendering summary judgment of non-infringement, the Court recognized that Spectrum's product does the opposite of what is disclosed and claimed because Spectrum's SDNA device did not preserve, but instead destroyed (or lysed) cells. Appx3787 (32:13-17); Appx3788 (34:9-12). Based on Genotek's allegation that the reagent composition of the accused SDNA device was the claimed reagent composition of the asserted '187 patent and Genotek's expert's testimony to the same effect, it was an undisputed fact that composition had the following effect on a sample: "When sputum is mixed with a composition of the present invention, cells are disrupted, nucleic acids are liberated from the cells, membranous material is solubilized, proteins are stripped from the nucleic acids, and protein digestion begins." Appx106 (quoting Appx137 (13:38-42).

Genotek asserts that it "produced evidence that Spectrum's products preserved one kind of antigen (TLR2 antigens)." Br. at 53. This argument is incorrect and also goes to an issue not appealed by Genotek, namely whether Genotek presented evidence raising a triable issue on the construction adopted by the district court.

In any event, the district court addressed Genotek's evidence and concluded that the evidence from both sides showed that Spectrum's product degraded cells instead of preserving them. Appx105-106.

The court did not, as Genotek alleges, require evidence that all antigens were preserved. Br. at 53. Instead, the court observed that the evidence that Genotek relied on, even construed in a way most favorable to Genotek, showed destruction of cells and degradation of multiple antigens. Appx107-108. Genotek argues that the definition in the specification only requires preventing cells "from having their antigens degraded" and asserts there is "no floor" to this requirement. Br. at 53. The district court disagreed, and explained its construction, provided by the explicit definition in the patent, required preventing cells and antigens (both plural) from degradation, which Genotek did not show. Appx107.

Genotek further argues that "[t]he district court similarly went astray in determining what 'preventing alternations in the cellular epigenome' requires." Br. 54. The district court, however, relied on the specification's definition of "epigenome." Appx111-112. That definition indicates the cellular epigenome includes specific covalent modifications of DNA and proteins, including methylation at the 5 position of cytosine in a CpG dinucleotide and acetylation of lysine residues of histones. Appx180 (16:27-33). In view of this express definition, the court granted summary judgement because Genotek's proffered evidence did not address these expressly identified modifications. Appx112-113. Genotek asserts that these are mere "examples" of modifications to the cellular epigenome. But the

'646 patent defines the epigenome as "the state or pattern of alteration" and identifies specific alterations that that are part of the epigenome. Appx180 (16:27-33). The district court correctly held that determining whether the epigenome was preserved required at least evidence of those specific alterations.

CONCLUSION

For the foregoing reasons, Spectrum respectfully requests that this Court affirm the judgment below.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 22, 2023

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SPECTRUM SOLUTIONS L.L.C.

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a). This brief contains 13,943 words, excluding the parts of the brief exempt by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point font Times New Roman.

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Dated: December 22, 2023

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